Complete Summary

GUIDELINE TITLE

Progesterone-only and non-hormonal contraception in the breast cancer survivor: joint review and committee opinion of the Society of Obstetricians and Gynaecologists of Canada and the Society of Gynecologic Oncologists of Canada.

BIBLIOGRAPHIC SOURCE(S)

McNaught J, Reid RL, Provencher DM, Lea RH, Jeffrey JF, Oza A, Swenerton KD. Progesterone-only and non-hormonal contraception in the breast cancer survivor: Joint Review and Committee Opinion of the Society of Obstetricians and Gynaecologists of Canada and the Society of Gynecologic Oncologists of Canada. J Obstet Gynaecol Can 2006 Jul;28(7):616-26. [55 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Prevention Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To examine the relationship between progestin-only contraception and breast cancer and to make recommendations regarding contraception for the breast cancer survivor

TARGET POPULATION

Women with a history of breast cancer (breast cancer survivors) who need contraception

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Depo-Provera (depot medroxyprogesterone acetate [DMPA]) contraceptive therapy
- 2. Use of progestin-only pill (POP)
- 3. Levonorgestrel-releasing intrauterine system (LNG-IUS)
- 4. Non-hormonal options for contraception including the copper intrauterine device (IUD), barrier methods (male and female condom, diaphragm, sponge, etc.), and permanent sterilization or natural family planning methods

MAJOR OUTCOMES CONSIDERED

Incidence of breast cancer among users of progestin-only contraception

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

PubMed and Medline databases were searched using the terms "breast cancer" and "progesterone," "contraception," "depot medroxyprogesterone acetate," "Micronor," "Mirena," and "subdermal implant." The citations were limited to the English language. References were searched for other relevant articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence*

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence from well-designed controlled trials without randomization.
- **II-2**: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.
- **II-3**: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
- *Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on the Periodic Health Exam.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations*

- A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination.
- D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.
- E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This Review and Committee Opinion has been reviewed and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada and of the Society of Gynecologic Oncologists of Canada.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The level of evidence (I-III) and classification of recommendations (A-E) are defined at the end of the "Major Recommendations" field.

In-Vitro and Animal Data

Summary Statement

Progesterone and progestins can have a proliferative, antiproliferative, or neutral effect on breast tissue, depending on the type, timing, and dose of progestin used. (\mathbf{I})

Human Data

Depot Medroxyprogesterone Acetate (DMPA)

Summary Statement

^{*}Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on the Periodic Health Exam.

Use of DMPA does not increase the risk of breast cancer in the general population. (II-2)

Recommendation

DMPA use in a breast cancer survivor can be considered in circumstances where contraceptive or non-contraceptive benefits outweigh any unknown potential increase in recurrence risk. (**III-C**)

Progestin-Only Oral Contraceptives

Summary Statement

Although not as well-studied as the combined oral contraceptive pill, progestinonly pills (POPs) do not appear to increase the risk of breast cancer in the general population. (**II-2**)

Recommendation

Use of POPs in a breast cancer survivor may be considered in a situation where known benefits outweigh any unknown potential increase in recurrence risk. (**III-C**)

Contraceptive Implants

Summary Statement

There is insufficient evidence to comment on risk or recurrence risk of breast cancer with contraceptive implants in the general population (**II-2C**) or among breast cancer survivors. (**III**)

Levonorgestrel-Releasing Intrauterine System (LNG-IUS)

Summary Statement

The limited data available suggest that the LNG-IUS does not seem to increase breast cancer risk in the general population. (**II-2**)

Recommendation

Use of the LNG-IUS in the breast cancer survivor can be considered if the unique contraceptive or non-contraceptive benefits outweigh the risk of an unknown effect on recurrence. (**III-C**)

Conclusions

Summary Statements

Sterilization and the copper intrauterine device (IUD) are the most reliable non-hormonal contraceptive methods. (**II-1**)

Other non-hormonal methods may also be appropriate given decreased fertility with advancing age and after chemotherapy. (**III**)

Further research into progestin-only contraception in the breast cancer survivor is needed. (**III**)

Recommendation

Non-hormonal contraceptive methods should be used as first-line options in the breast cancer survivor. (**III-C**)

Definitions:

Level of Evidence*

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence from well-designed controlled trials without randomization.
- **II-2**: Evidence from well-designed cohort (prospective or retrospective) or case-control analytic studies, preferably from more than one centre or research group.
- **II-3**: Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Classification of Recommendations**

- A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination.
- D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.
- E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

CLINICAL ALGORITHM(S)

^{*}The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on the Periodic Health Exam.

^{**}Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on the Periodic Health Exam.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Providing reliable contraception and non-contraceptive benefits to breast cancer survivors versus breast cancer recurrence risk

POTENTIAL HARMS

- Breast tenderness can be one of the initial nuisance side effects of the levonorgestrel-releasing intrauterine system (LNG-IUS), so it would seem that there is some systemic hormonal effect on the breast, at least in the first few months after insertion when levonorgestrel levels are highest.
- In circumstances where a progestin-only method such as the LNG-IUS offers
 unique contraceptive or noncontraceptive benefits, this method may be
 appropriate as long as the woman understands that available data remain
 insufficient to provide unequivocal proof of safety. Depot
 medroxyprogesterone acetate (DMPA) and the progestin-only pill expose the
 breast to relatively high levels of synthetic progestins, and, given the
 uncertainties about long-term safety in breast cancer survivors, these
 methods are probably best avoided until more information is available.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Jul

GUIDELINE DEVELOPER(S)

Society of Gynecologic Oncologists of Canada - Disease Specific Society Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Obstetricians and Gynaecologists of Canada

GUIDELINE COMMITTEE

Society of Obstetricians and Gynaecologists of Canada and of the Society of Gynecologic Oncologists of Canada Ad Hoc Committee on Breast Cancer

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Society</u> of Obstetricians and Gynaecologists of Canada Web site.

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 4, 2009. The information was verified by the guideline developer on March 4, 2009.

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